



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/051,835	01/16/2002	Amy W. Lasek	PA-0044 US	1180
27904	7590	10/03/2003	EXAMINER	
INCYTE CORPORATION (formerly known as Incyte Genomics, Inc.) 3160 PORTER DRIVE PALO ALTO, CA 94304			ZHOU, SHUBO	
			ART UNIT	PAPER NUMBER
			1631	

DATE MAILED: 10/03/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/051,835

Applicant(s)

LASEK ET AL.

Examiner

Shubo "Joe" Zhou

Art Unit

1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-20 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

Detailed Action

The art unit designated for this application has changed. Applicant(s) are hereby informed that future correspondence should be directed to Art Unit 1631.

Restriction/Election Requirement

Restriction to one of the following inventions is required under 35 U.S.C. § 121:

- I. Claims 1-6, drawn to an array of polynucleotides, classified in Class 435, subclass 6.
 - II. Claim 7-9, drawn to a high throughput method for detecting differential expression of genes, classified in class 435, subclass 6.
 - III. Claims 10-11, drawn to a high throughput method for screening a plurality of molecules to identify a compounds that specifically binds to a cDNA, classified in class 435, subclass 6.
 - IV. Claims 12-14, drawn to a polynucleotide or vectors or host cells containing the same, classified in class 536, subclass 23.1, 320.1.
 - V. Claim 15, drawn to a method of making a protein, classified in 435, subclass 69.1.
 - VI. Claim 16, drawn to a polypeptide or protein, classified in Class 530, subclass 300.
 - VII. Claims 17-18, drawn to method of using a protein to screen a library to find compounds that bind to the protein, classified in class 435, subclass 5.
 - VIII. Claim 19, drawn to a method of making an antibody, classified in class 424, subclass 130.
 - IX. Claim 20, drawn to an antibody, classified in class 530, subclass 387.1.
-

The inventions are distinct, each from the other because of the following reasons:

The inventions of Groups (I-IV), Groups (V-VII), and Group (VIII-IX) are independent distinct inventions because they are directed to different chemical types or other subject matter regarding the critical limitations therein. For Groups (I-IV), the critical feature is nucleic acids; for Groups (V-VII), the critical feature is a polypeptide; for Groups (VIII-IX), the critical feature is an antibody. It is acknowledged that various processing steps may cause a polypeptide to be directed as to its synthesis by a polynucleotide, however, the completely separate chemical types of the inventions of the nucleic acid, polypeptide, antibody and any chemical feature that binds to a polypeptide of the Groups supports the undue search burden if they were examined together. Additionally, polynucleotides, polypeptides, antibodies and binding partners have been most commonly, albeit not always, separately characterized and published in the biochemical literature, thus significantly adding to the search burden if examined together as compared to being searched separately. Also, it is pointed out that processing that may connect two Groups does not prevent them from being viewed as distinct because enough processing can result in producing any composition from any other composition if the processing is not limited as to additions, subtractions, enzyme action, etc. Thus, the three groupings of Groups (I-IV), Groups (V-VII), and Group (VIII-IX) are independent and/or distinct invention types for restriction purposes.

The inventions of Group I and Groups II-III are related as product and distinct processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case the nucleic acids of Group I can be used in the distinct processes of the inventions of Groups II and III, i.e. detecting differential

expression of genes (II) and screening a plurality of molecules to identify a compounds that specifically binds to a cDNA (III), which are clearly distinct processes.

Groups I and IV are distinct. While they both belong to polynucleotides, they have distinct functions. The polynucleotide of group IV can be used to make a polypeptide, made a probe or an antisense RNA, while the array of group I can be used to identify the expression profile of genes containing on the array.

The inventions of Group VI and VII are related as product and distinct processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case the protein of Group VI can be used in the process of the inventions of group VII, i.e. using the protein to screen for compounds that bind tot the protein. Alternatively, the protein can be used to make an antibody, which is clearly a distinct usage.

The inventions of Groups VI and V are related as product and distinct process of making. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process as claimed can be used to make other and materially different product or (2) the product as claimed can be made by another and materially different process (MPEP §806.05(f)). In the instant case, the polypeptides of Group VI can be produced by distinct process of invention of Group V, or alternatively, the polypeptides can be produced by *in vitro* coupled transcription/translation processes, or chemical synthesis.

The inventions of Groups IX and VIII are related as product and distinct process of making. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process as claimed can be used to make other and materially different product or (2) the product as claimed can be made by another and materially different process (MPEP

§806.05(f)). In the instant case, the antibody of Group IX can be produced by distinct process of invention of Group VIII, i.e. using a protein, or alternatively, the antibody can be produced by chemical synthesis if the sequence is known because the chemical nature of the antibody is a protein.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR § 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

Applicant is further reminded that a fully responsive communication will comprise a proper election of a group and sequence as set forth above. Examination cannot proceed without a complete response.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CFR § 1.6(d)). The CM1 Fax Center number is either (703) 308-4242 or (703)305-3014.

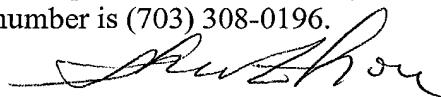
Art Unit: 1631

Any inquiry concerning this communication or earlier communications from the examiner should be directed to:

Shubo "Joe" Zhou, Ph.D., whose telephone number is (703) 605-1158. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (703) 308-4028.

Any inquiry of a general nature or relating to the status of this application should be directed to Patent Analyst Tina Plunkett whose telephone number is 703-305-3524, or to the Technical Center receptionist whose telephone number is (703) 308-0196.

A handwritten signature in black ink, appearing to read "Shubo Zhou", is positioned above the printed name and title.

Shubo "Joe" Zhou, Ph.D.
Patent Examiner